

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF TEXAS  
TYLER DIVISION**

**MERCK & CIE,  
SOUTH ALABAMA MEDICAL SCIENCE  
FOUNDATION and  
PAMLAB L.L.C.**

**Plaintiffs,**

**-VS.-**

**MACOVEN PHARMACEUTICALS, GNOSIS  
S.P.A. GNOSIS USA INC. and  
GNOSIS BIORESEARCH S.A.,**

**Defendants.**

**Civil Action No. 6:12-cv-0027**

**JURY TRIAL DEMANDED**

**PROTECTIVE ORDER**

Upon stipulation of the Parties for an order pursuant to FED. R. CIV. P 26(c) that confidential information be disclosed only in designated ways, the Court enters the following Consent Protective Order:

1. As used in this Consent Protective Order, the terms identified in this Paragraph are defined as follows:

- a. "Action" means the litigation captioned Merck & Cie, South Alabama Medical Science Foundation and PamLab L.L.C. v. Macoven Pharmaceuticals, Gnosis S.P.A., Gnosis USA Inc. and Gnosis Bioresearch

S.A., Civil Action no. 6:12-cv-0027, pending in the United States District Court for the Eastern District of Texas;

- b. “Attorneys” means counsel of record in this Action;
- c. “Classified Information” means any information of any type, kind or character that is designated as “Confidential” or “HIGHLY Confidential – Outside Attorneys’ Eyes Only” by any of the supplying or receiving Parties, whether it be a document, information contained in a document, information revealed during a deposition, information revealed in an interrogatory answer or otherwise;
- d. “Documents” means all materials within the scope of FED. R. CIV. P. 34;
- e. “Outside Vendors” means consultants or entities retained by outside counsel to assist or serve as jury consultants, translators, interpreters, graphic artists or document/information consultants, messenger, copy, coding, and other clerical-services vendors not employed by a Party or its Attorneys; and
- f. “Written Assurance” or “Undertaking” means an executed document in the form attached as Exhibit A.

2. A Party may designate a document “Confidential” or “HIGHLY Confidential – Outside Attorneys’ Eyes Only” to protect information within the scope of FED. R. CIV. P. 26(c).

3. A Party may designate as “Confidential” only that information that it in good faith believes contains information of a confidential or sensitive nature, including but not limited to

non-public, proprietary, or confidential business or financial information. A Party may designate as “HIGHLY Confidential – Outside Attorneys’ Eyes Only” only that information that it in good faith believes the disclosure of which to representatives of the adverse Party would cause it competitive harm, including but not limited to strategic plans, marketing plans, research and development information, proprietary technical documents, financial information, sales information, confidential information obtained from a nonparty pursuant to a current Nondisclosure Agreement, sales and financial projections, confidential meeting minutes, results of internal investigations, and other commercially sensitive competitive information that the supplying party maintains as highly confidential in its business. A party may designate as “Prosecution Bar” only that information that it in good faith believes the disclosure of which to representatives of the adverse Party would cause it competitive harm in prosecution of U.S. patents, including the reexamination proceedings of the current Patents-In-Suit. For the avoidance of doubt, the “Prosecution Bar” excludes publicly available information.

4. All Classified Information shall be used solely for the purpose of this action, and no person receiving such documents shall, directly or indirectly, use, transfer, disclose, or communicate in any way the documents or their contents to any person other than those specified in paragraph 5 below. Any other use is prohibited.

5. Access to information designated as “Confidential” shall be limited to:
- a. the Court and its staff;
  - b. Attorneys, their law firms, and their Outside Vendors;

- c. Up to three (3) designated in-house attorneys or employees who are responsible for monitoring and/or supervising this action on behalf of a Party and the secretarial, clerical, paralegal and other supporting personnel (“legal department members”) of said attorney or employee with monitoring and/or supervising responsibilities working on this case; the person designated on behalf of each party under this subparagraph 5(c) shall take appropriate steps to segregate Classified Information from other company and other department records and to limit access to such materials only to the persons designated herein and the legal department members. The parties shall identify the in-house attorneys or employees who are responsible for monitoring and/or supervising this action prior to the sharing of Classified Information with those individuals.
- d. Outside experts or consultants retained or in good faith proposed to be retained for the purpose of assisting attorneys in the prosecution or defense of this action or testifying at trial and their secretarial, clerical, and other supporting personnel, to the extent deemed necessary in good faith by the retaining counsel to enable a consultant or expert to evaluate the proposed retention and/or provide such assistance or testimony. Disclosure of information designated as “Confidential” to such an expert or consultant shall be made only after: (i) Counsel for the retaining party provides to producing party a declaration from the expert or consultant in the form attached hereto as Exhibit A, that he or she is not involved directly or

indirectly as an employee, contractor or consultant, in the design, development, manufacture, marketing and/or sale of products that directly compete with the products of the party to whom the Confidential Information belongs, and a completed and signed undertaking in the form of Exhibit B attached hereto; (ii) Counsel for the retaining party provides to producing party a copy of the expert's current curriculum vitae, a list of past and present employers, a list of cases the expert or consultant has testified as an expert at trial or by deposition within the preceding four (4) years, and an indication of whether the expert has worked or consulted for, or on behalf, of a producing party in the past; and (iii) the expiration of seven (7) business days (or earlier if the Parties so agree in writing between themselves), commencing with the receipt by counsel for the producing Party of the items in (i) and (ii). During the seven (7) business day period, counsel for the producing Party may object in writing to the disclosure of "Confidential" Information to this expert or consultant for good cause, e.g., an identified conflict of interest, stating with particularity the ground(s) of the objection. If counsel for the producing Party fails to object to such disclosure before the expiration of the prescribed seven (7) day period, any objection to such disclosure shall be deemed waived, except as to a basis for objection that was not known and could not reasonably have been discovered in said period. In the event that a good-faith objection is made within the prescribed period, there shall be no

disclosure of “Confidential” Information to the expert or consultant until there is an express written agreement of the Parties or order of this Court removing the objection. The Party seeking disclosure to an objected-to expert or consultant shall have the obligation to seek an order of Court removing the objection. Identification or disclosure of the identity of an expert or consultant pursuant to the terms of this provision shall not constitute a waiver of the work produce privileged related to that consultant’s activities.

- e. Persons shown on the face of the document to have authored or received it, or employees, consultants or experts testifying on behalf of the Party from whose files the document was produced;
- f. Court reporters retained to transcribe testimony.

6. Access to information designated as “HIGHLY Confidential – Outside Attorneys’ Eyes Only” and/or “Prosecution Bar” shall be limited to persons identified in Subparagraphs 5.a, 5.b, 5.d, 5.e, and 5.f above. Furthermore, the provisions of Subparagraphs 5.d, addressing the requirements for disclosure of information designated as “Confidential” to outside experts or consultants equally apply to information designated as “HIGHLY Confidential – Outside Attorneys’ Eyes Only.”

7. Unless otherwise permitted in paragraph 9 below, no attorney or other individual who has accessed any other Producing Party’s “Prosecution Bar” information shall be involved, thereafter, in any Prosecution Activity (as defined hereinbelow) relating to patent claims reciting

any reduced folate products or methods of using the same. This prohibition (1) shall continue for a period of one year after the conclusion of this litigation with respect to any party for whom such individual is acting and (2) shall be personal to such attorney or other individual and shall not be imputed to any other person.

8. Prosecution Activity shall mean: (1) preparing and/or prosecuting any patent application (or portion thereof), whether design or utility, and either in the United States or abroad on behalf of a patent applicant, patentee or assignee of patentee's rights; (2) preparing and/or prosecuting patent claim(s) on behalf of a patent applicant, patentee or assignee of patentee's rights, including in any reissue, interference or reexamination application or proceedings, and/or in any opposition, cancelation or other challenge to any patent or application, in the United States or abroad; or (3) providing advice, counsel, supervision or suggestions regarding, or in any other way influencing, claim scope and/or language, embodiment(s) for claim coverage, claim(s) for prosecution, or products or processes for coverage by claim(s) on behalf of a patent applicant, patentee or assignee of patentee's rights. For clarity and not by way of limitation, each of (1)-(3) applies to any patent application (or portion thereof), whether design or utility, either in the United States or abroad; any opposition or cancelation; or any interference of any patent or patent application.

9. The provisions of paragraphs 7 and 8 above shall not prevent counsel of record in this action who has seen or reviewed the content of information designated hereunder as "Prosecution Bar" from (1) reviewing communications from the United States Patent Office ("PTO") or any other foreign patent office or tribunal regarding a re-examination, or any other

proceeding before the PTO or any foreign patent office or tribunal in which a patent or pending application is challenged, or from discussing claim interpretation issues or ways of distinguishing claims in any such reexamination or other proceeding before the PTO or any other foreign patent office or tribunal from any cited prior art, including with patent prosecution counsel or agents thereof handling such proceeding; or (2) providing advice regarding claim scope and/or language, claim(s) for prosecution, or products or processes for coverage by claim(s) on behalf of a patent applicant, patentee, assignee, or licensee of patentee's rights provided such advice is based on publicly available information and/or information lawfully obtained by patent applicant, patentee, assignees of patentee or its licensees. In no way can any such advice be based on "Prosecution Bar" information. Further, counsel of record in this action may not prosecute any such reexamination or reissue and may not reveal the content of information designated hereunder as "Prosecution Bar" to reexamination or reissue patent counsel or agents.

10. Third Parties producing documents in the course of this Action may also designate the materials produced as "Confidential" or "HIGHLY Confidential – Outside Attorneys' Eyes Only" subject to the same protections and constraints as the Parties to the action. The Parties shall have the right to review such Third Party production and to in good faith and reasonably designate any portions thereof "Confidential" or "HIGHLY Confidential – Outside Attorneys' Eyes Only," subject to and as provided in this Order. A copy of this Consent Protective Order shall be served along with any subpoena served in connection with this action.

11. Nothing in this Consent Protective Order shall be construed to require the disclosure of information, documents or things protected from disclosure by the attorney-client



privilege, the attorney-work product immunity or any other applicable privilege or immunity. A producing Party may produce a redacted version of information, documents or things that it contends is protected from disclosure by the attorney-client privilege, the attorney-work product immunity or any other identified applicable privilege or immunity, identifying where the privileged or immune material was redacted with the designation "Redacted-Privileged." In the event that a Party inadvertently or mistakenly produces information, documents or things that are protected from disclosure under the attorney-client privilege, work-product immunity or any other identified applicable privilege or immunity, such production shall not prejudice such claim or otherwise constitute a waiver of any claim of attorney-client privilege, work-product immunity or any other identified applicable privilege or immunity. A producing Party may at any time notify the receiving Party of the inadvertent production in writing and request that the inadvertently produced information, documents or things be returned to the producing Party. Within three (3) business days of receiving such notice and request, the receiving Party shall return the inadvertently or mistakenly produced information, documents or things identified by the producing Party. The receiving Party may challenge the claim of privilege or immunity asserted by the producing Party upon motion to the Court only after the receiving Party has returned the inadvertently produced document to the producing Party, with the exception that the receiving Party may retain one copy of such material for the purpose of submitting such material to the Court under seal. The receiving Party shall also destroy extra copies or summaries of, or notes relating to, any such inadvertently or mistakenly produced information.

12. All depositions or portions of depositions taken in this action that contain confidential information may be designated "Confidential" or "HIGHLY Confidential – Outside

Attorneys' Eyes Only" or "Prosecution Bar" and thereby obtain the protections accorded other "Confidential" or "HIGHLY Confidential – Outside Attorneys' Eyes Only" documents. Confidentiality designations for depositions shall be made either on the record or by written notice to the other party within ten (10) business days of receipt of the final transcript by the designating Party's counsel. Unless otherwise agreed, depositions shall be treated as "HIGHLY Confidential – Outside Attorneys' Eyes Only" and "Prosecution Bar" during the ten (10)-day period following receipt of the rough transcript, or until receipt of the notice referred to in this subparagraph, whichever occurs sooner. The deposition of any witness (or any portion of such deposition) that encompasses "Confidential" or "HIGHLY Confidential – Outside Attorneys' Eyes Only" or "Prosecution Bar" information shall be taken only in the presence of persons who are qualified to have access to such information, unless otherwise agreed to by the parties.

13. Any Party who inadvertently fails to identify documents as "Confidential" or "HIGHLY Confidential – Outside Attorneys' Eyes Only" or "Prosecution Bar" shall, promptly upon discovery of its oversight, provide written notice of the error and substitute appropriately-designated documents. Any Party receiving such improperly-designated documents shall retrieve such documents from persons not entitled to receive those documents and, upon receipt of the substitute documents, shall return or destroy the improperly-designated documents.

14. This Protective Order shall not prevent any Party from using Classified Information in any affidavit, brief, memoranda of law, or other papers filed with the Court. However, the Party using such Classified Information must cause such information to be filed with the Court under separate cover and placed under seal.

15. Any Party may request a change in the designation of any information designated “Confidential” or “HIGHLY Confidential – Outside Attorneys’ Eyes Only” or “Prosecution Bar.” Any such document shall be treated as originally designated unless and until the change is completed. If the requested change in designation is not agreed to, the Party seeking the change may move the Court for appropriate relief, providing notice to any third party whose designation of produced documents as “Confidential” or “HIGHLY Confidential – Outside Attorneys’ Eyes Only” in the action may be affected. The Party asserting that the material is Classified shall have the burden of proving that the information in question is within the scope of protection afforded by FED. R. CIV. P. 26(c).

16. Unless the parties otherwise agree, within sixty (60) days of the termination of this action, including any appeals, each Party shall either destroy or return to the producing party all documents designated by the producing party as “Confidential” or “HIGHLY Confidential – Outside Attorneys’ Eyes Only” or “Prosecution Bar” and all copies of such documents, and shall destroy all extracts and/or data taken from such documents. Each Party shall provide a certification as to such return or destruction within the sixty (60)-day period. However, Attorneys shall be entitled to retain a set of all documents filed with the Court and all correspondence generated in connection with the action.

17. Any Party may apply to the Court for a modification of this Consent Protective Order and nothing in this Consent Protective Order shall be construed to prevent a Party from seeking such further provisions enhancing or limiting confidentiality as may be appropriate.

18. No act taken in accordance with this Consent Protective Order shall be construed as a waiver of any claim or defense in the action or of any position as to discoverability or admissibility of evidence.

19. Nothing in this Consent Protective Order shall restrict the use or disclosure by any Party of its own Classified Information.

20. If any of the specific materials or information that has been designated as "Confidential" or "HIGHLY Confidential – Outside Attorneys' Eyes Only" or "Prosecution Bar" under the terms of this Consent Protective Order appear or are found in a publicly available form without fault on the part of the receiving Party herein, then such information and materials shall no longer be subject to the restrictions of this Consent Protective Order.

21. In the event any person, Party, witness or entity violates or threatens to violate the terms of this Consent Protective Order during the period of time the Court has jurisdiction over this matter, the Parties agree that the aggrieved Party may immediately apply to the Court to obtain injunctive relief, or any other appropriate relief, against any such violation or threatened violation. If the violation or threatened violation occurs after the Action is completed, the aggrieved Party can seek any appropriate remedies permitted under the law, including, without limitation injunctive relief, in any court of competent jurisdiction.

22. The obligations imposed by this Consent Protective Order shall survive the termination of this action except with respect to those documents and information that become a matter of public record through no fault of the receiving party.

**So ORDERED and SIGNED this 7th day of September, 2012.**

Stipulated to:

**Counsel for Plaintiffs**

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*Attorneys for Gnosis, S.p.A., Gnosis USA  
Inc., and Gnosis Bioresearch S.A.*

IT IS SO ORDERED:

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF TEXAS  
TYLER DIVISION

MERCK & CIE,  
SOUTH ALABAMA MEDICAL SCIENCE  
FOUNDATION and  
PAMLAB L.L.C.

Plaintiffs,

-VS.-

MACOVEN PHARMACEUTICALS, GNOSIS  
S.P.A. GNOSIS USA INC. and  
GNOSIS BIORESEARCH S.A.,

Defendants.

Civil Action No. 6:12-cv-0027

JURY TRIAL DEMANDED

DECLARATION OF \_\_\_\_\_

1. I, \_\_\_\_\_, declare and say as follows.
2. I am not involved directly or indirectly as an employee, contractor or consultant, in the design, development, manufacture, marketing and/or sale of products that directly compete with the products of \_\_\_\_\_, to whom the Classified Information belongs,
3. Pursuant to 28 U.S.C. § 1746, I, \_\_\_\_\_, certify under penalty of perjury that the foregoing is true and correct. Executed on this the \_\_\_\_ day of \_\_\_\_\_, \_\_\_\_.

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**Defendants.**

**Civil Action No. 6:12-cv-0027**

**JURY TRIAL DEMANDED**

**WRITTEN ASSURANCE FOR CONSENT PROTECTIVE ORDER**

1. I, \_\_\_\_\_, acknowledge that I have read and fully understand the terms of the Consent Protective Order filed in Civil Action No. 12-cv-0027, pending in the United States District Court for the Eastern District of Texas.

2. I agree to comply with and be bound by the obligations and conditions of the Consent Protective Order.

3. I further agree to maintain as confidential all the Protected Information designated "Confidential" or "HIGHLY Confidential – Outside Attorneys' Eyes Only" obtained pursuant to the Consent Protective Order, or the contents of such documents, to any person other than those



specifically authorized by the Consent Protective Order. I shall not copy or use such documents except for the purposes of this action and pursuant to the Consent Protective Order.

4. As soon as practical, but no later than thirty (30) days after final termination of this action, I further agree to return any and all Protected Information designated "Confidential" or "HIGHLY Confidential – Outside Attorneys' Eyes Only", and all copies, excerpts, summaries, notes, digests, abstracts, and indices related to such documents, disclosed to me pursuant to the Consent Protective Order to the attorney from whom I have received such Protected Information.

5. In addition, I hereby submit to the jurisdiction of the United States District Court for the Eastern District of Texas for the purpose of any proceedings relating to the performance under, compliance with or violation of the Consent Protective Order.

DATED: \_\_\_\_\_

\_\_\_\_\_  
Name (signature)

\_\_\_\_\_  
Name (printed)